

Serial No.: 10/039,367
Docket No.: ECV-5608
Amendment dated October 6, 2004
Responsive to Office Action of July 6, 2004

REMARKS

Reconsideration of the application in view of the following remarks is respectfully requested.

Prior to the present Office Action, claims 1-92 were pending, with claims 21 and 25-92 being withdrawn as pertaining to a non-elected invention. Claims 11-12, 15-18, and 36-92 have been canceled, claims 93-103 have been added, and therefore claims 1-10, 13-14, 19-35 and claims 93-103 are now pending (with claims 21 and 25-35 remaining withdrawn).

With respect to the Restriction Requirement and the subsequent Election, Applicants affirm the election of the invention of Group I, embodied in claims 1-20 and 22-24, *without traverse*. Applicants respectfully request reinstatement of dependent claims 21 and 25-35 if and when parent claim 1 is allowed.

Serial No.: 10/039,367
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Claim rejections under 35 U.S.C. § 112

Claims 1-20 and 22-24 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Specifically, the Examiner finds various terms in claim 1 indefinite, and further that some of the claims contain overlapping ranges. The terms in claim 1 have been further defined, 5 and the "second temperature" parameter is now introduced in claim 6. Applicants are not sure what the Examiner objects to with regard to overlapping ranges of temperature. The Examiner states that the claims include a process in which the first temperature is 69.5° C and the second temperature is a 70° C, which "is a normal variation even when using a thermostat." Applicants point out that claim 6 requires the affirmative step of adjusting the temperature of the 10 glutaraldehyde solution to the second temperature. Even if the temperature is adjusted by a small amount (e.g., 0.5° C), this is a positive and definite limitation.

With regard to claim 2, it has been amended to remove the pH ranges and the solution color range.

With regard to claim 10, the range of the second temperature is no longer open-ended.

15 With regard to claims 13-17, most have been canceled and claims 13-14 have been amended to specify that the tissue is fully fixed prior to step (c) of claim 1. This procedure is supported in the specification at paragraph [0045].

Claim 18 has been canceled.

In claim 20, the term "further" and the "second temperature" limitation have been 20 deleted.

In claim 24, the generic chemical name of Tween 80 has been added in parentheses.

Claim rejections under 35 U.S.C. § 103 in view of McIlroy, et al.

Claims 1, 3, 7-9, 11, 13-16, and 18 stand rejected under 35 U.S.C. §103(a) as being 25 obvious over McIlroy, et al. (USPN 6,093,530). In response, claim 1 has been amended and a clean version is reprinted below:

Serial No.: 10/039,367

Docket No.: ECV-5608

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1. A method for mitigating post-implantation calcification of a bioprosthetic material, said method comprising the steps of:

- (a) heating a glutaraldehyde solution having a pH of between 7.2-7.8 to a first temperature above 20° C. for a first period of time of at least one hour until the pH of the glutaraldehyde solution has been reduced to between 5-7; and,
- (c) contacting a quantity of biological tissue that contains connective tissue protein with the pH-reduced glutaraldehyde solution for a second period of time of at least one hour.

10 Claim 1 thus now includes a portion of original claim 2, which was not rejected as being obvious over McIlroy, et al. In particular, the glutaraldehyde solution is heated for a period of time until its pH has been reduced from between 7.2-7.8 to between 5-7. The section 112 issues have been addressed along with this amendment, and Applicants assert that claim 1 is allowable over McIlroy, et al. McIlroy, et al. discuss in Example 1 fixation of biomaterial in glutaraldehyde buffered at pH 7.4. There is no mention of heating the glutaraldehyde solution for a period of time prior to immersion of the biomaterial, nor is there mention of altering the pH of a glutaraldehyde solution, or heating a glutaraldehyde solution until its pH drops. Accordingly, claim 1 and its dependents are believed allowable over McIlroy, et al.

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20 **Claim rejections under 35 U.S.C. § 103 in view of Carpentier, et al.**

Claims 1, 3, 7, 11-16, and 18 stand rejected under 35 U.S.C. §103(a) as being obvious over Baxter International Inc. (WO 96/04028). This PCT application corresponds to a US application that has matured into US Patent No. 6,561,970, and which is referred to herein as Carpentier, et al.

25 The present Applicants are the same as the applicants of Carpentier, et al., and the present application as embodied in amended claim 1 is believed allowable over Carpentier, et al. Specifically, Carpentier, et al. provide a method of "placing the biological tissue in contact with

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Docket No.: ECV-5608
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glutaraldehyde or another chemical fixative and then heating the glutaraldehyde or other fixative..." (first paragraph of the summary). In each example, the tissue is placed within the glutaraldehyde or other solution and then heated. Furthermore, there is no mention of adjusting the pH, let alone adjusting the pH to between 5-7. Accordingly, Applicants assert that claim 1 and its dependents are allowable over Carpentier, et al.

Claim rejections under 35 U.S.C. § 103 in view of McIlroy, et al. or Carpentier, et al. in combination with Nashef, et al.

Claims 22-24 stand rejected under 35 U.S.C. §103(a) as being obvious over McIlroy, et al. or Carpentier, et al., and further in view of Nashef, et al. (USPN 4,885,005). Applicants assert that, based on the amendments and remarks above, claim 1 is allowable over both McIlroy, et al. and Carpentier, et al. Accordingly, the rejection of dependent claims 22-24 is believed obviated.

New claims

Claims 93-103 have been added to more comprehensively cover the elected invention. These claims merely added process parameters that are fully supported in the present application.

Withdrawn claims

Applicants respectfully request that withdrawn claims 21 and 25-35 be reinstated as depending from allowable claim 1.

Fees Due to File This Amendment

Prior to the pending Office Action, a fee was paid for the original 92 claims, with 4 of them being independent claims. The aforementioned claim additions and cancellations have not resulted in more than the original number of claims, and thus no claim fees are believed to be due to file this amendment.

Serial No.: 10/039,367
Docket No.: ECV-5608
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Conclusion

Accordingly, in view of the above amendments and remarks, it is submitted that this application is now ready for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject 5 application, the Examiner is invited to call the undersigned at (773) 857-7634.

If an appropriate payment does not accompany or precede this submission, the Commissioner is hereby authorized to charge any required fees, such as under 37 C.F.R. §§ 1.16 or 1.17, including any petition for extension of time, or to credit any overpayment, to Deposit Account No. 50-1225.

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Respectfully submitted,

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